Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 20 working days after the meeting, at a cost of 10 cents per page, or examine a transcript of the meeting after December 17, 2001, at the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23805 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1538]

Draft Guidance for Industry; Electronic Records; Electronic Signatures, Validation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation.'' The draft guidance describes the agency's current thinking on issues pertaining to validating computer systems subject to part 11 (21 CFR part 11) requirements, to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities. Such validation is a requirement of part 11 of title 21 of the Code of Federal Regulations.

DATES: Submit written or electronic comments on the draft guidance by Decmeber 24, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Information and Quality Assurance (HFC–240), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, room 1060, Rockville, MD 20852. Submit electronic comments to *http://www.FDA.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Motise, Office of Enforcement (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0383, e-mail: *pmotise@ora.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Validation.'' In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper (''part 11''). The preamble to part 11 stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance addresses issues pertaining to the validation of computer systems used to create, modify, maintain, archive, retrieve, or transmit electronic records and electronic signatures subject to part 11. Part 11 requires such validation, and the guidance is intended to assist people who must meet this requirement; it may also assist FDA staff who apply part 11 to persons subject to the regulation.

The draft guidance provides specific information on key validation principles, and it addresses some frequently asked questions. However, it is not intended to cover everything that computer systems validation should encompass in the context of electronic record/signature systems. In addition to addressing key validation principles, the draft document discusses considerations regarding off the shelf software and the Internet.

By direct reference, this draft guidance incorporates definitions of terms contained in a companion draft guidance, ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms.'' Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of that companion draft document, and is offering the opportunity to comment on it, as well.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on validating computerized systems subject to part 11. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ora/compliance_ref/Part11.*

Dated: August 23, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–23698 Filed 9–21–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1543]

Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms.'' The draft guidance defines terms that will be used in FDA's guidances that describe the agency's current thinking on principles and procedures for creating, modifying, maintaining, archiving, retrieving, and transmitting electronic records and electronic signatures in order to ensure that electronic records